UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,784	11/03/2003	Jacques M. Dulin	7175-004US	5515

35531 7590 04/17/2007

JACQUES M. DULIN, ESQ. DBA
INNOVATION LAW GROUP, LTD.
237 NORTH SEQUIM AVENUE
SEQUIM, WA 98382-3456

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,784	DULIN, JACQUES M.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007 and 26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are presented for examination.

Applicant's petition to make the instant application special pursuant to 37 C.F.R. 1.102(c)(1) and MPEP §708.02(IV) has been previously acknowledged by the Examiner.

In a telephone conversation Wednesday, April 4, 2007, Applicant's representative, Jacques Dulin, confirmed that the status of present claim 5 is pending but withdrawn. Applicant's representative stated that the strikeout of text contained in claim 5 was in error and was not intended to imply a cancellation of the claim.

In the same telephone conversation, Applicant's representative and Examiner Royds agreed to postpone holding an interview for the instant application until Applicant's representative was in receipt of a written response to the amendment and Declaration under 37 C.F.R. 1.132 in the interest of holding a constructive discussion of the merits of the case. Should Applicant feel that an interview of the case would advance prosecution, Applicant is invited to contact the Examiner to arrange a mutually convenient time for such an interview.

Applicant's Amendment and Declaration of Dr. Milo Novotny filed February 26, 2007 in response to the notice of non-compliant amendment dated February 23, 2007 have each been received and entered into the instant application.

Claims 1-15 are pending and under examination. Claim 5 remains pending but withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1, 10 and 13 are amended.

Applicant's arguments, filed February 26, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Requirement for Restriction/Election

Applicant's remarks regarding the requirement for restriction/election have been noted.

Claims 1-4 and 6-15 remain under examination. Claim 5 remains properly withdrawn. The restriction requirement remains proper and **finality is maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended part (b) of present independent claim 1 to now read, "a topical oral medication treatment composition effective to treat said adverse periodontal conditions carried by and releasably retained in said roll in an extended-release, single –use dosage amount in the range of .75-3 ml that is therapeutically effective to treat said adverse periodontal conditions", and has amended part (ii) of present independent claim 10 to now read, "a topical oral medication treatment composition in fluid or gel form in an amount effective to treat said adverse periodontal conditions carried by and releasably retained in said roll in an extended-release, single use dosage amount in the range of .75-3 ml that is therapeutically effective to treat said adverse periodontal conditions."

In particular, though Applicant's amendment to present claims 1 and 10 to remove the word "absorbed" and replace it with the word "retained" has been noted, it remains that it is unclear exactly what Applicant intends by the phrase "releasably retained". Merriam-Webster (Online, 2007) defines release as (previously cited by Examiner), "to set free from restraint, confinement, or servitude; to let go", and retain as, "to keep in possession or use; to hold secure or intact." In other words, "release" and

"retain" are, effectively, antonyms of one another and, therefore, the meaning intended by the phrase "releasably retained" is ambiguous and renders the scope of the subject matter for which Applicant is seeking protection unclear. Accordingly, the skilled artisan would not have been reasonably apprised of the meaning of this phrase and, in turn, the metes and bounds of the claimed subject matter.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Applicant's Remarks Regarding the Previous 112, Second Paragraph, Rejection of the Phrase "Releasably Absorbed"

Applicant states at page 10 of the remarks, "Please note the Specification discloses the claimed delivery units as having the property of "absorbing and releasably retaining treatment solution" on page 8, lines 6 and 7. Accordingly, the deletion of 'absorbed' and insertion of –retained—is supported, and renders the rejection moot. Note that the buccinator muscle squeezes out the medicated fluid to lave the diseased tissues. The Specification refers to the fluid as expressed from the rolls. That is the concept of releasing the fluid contained (absorbed) by the rolls."

The Examiner notes such remarks, but respectfully maintains that the phrase "releasably retained" does not clearly set forth the concept that Applicant intends, i.e., that the roll absorbs and retains the treatment solution and then releases it upon insertion into the oral cavity. Applicant may wish to consider removing the phrase "releasably retained" and amending part (b) of claim 1 to read: ---a topical oral medication treatment composition effective to treat said adverse periodontal conditions carried by and ~~releasably~~ retained in said roll <u>for release into the oral cavity</u> in an extended-release, single use dosage amount in the range of .75-3 ml that is therapeutically effective to treat said adverse periodontal conditions---.

Should Applicant accept such an amendment, Applicant is advised to amend present claim 10 in a manner consistent with the suggestion provided *supra*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

It is noted that Applicant repeatedly references "seven different 103 rejections" in the remarks, (see, e.g., pages 10-11, etc.). However, *five* rejections were set forth under 35 U.S.C. 103(a) and are herein repeated below:

Claims 1-4 and 6-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997), for the reasons of record set forth at pages 9-11 of the previous Office Action dated October 25, 2006, of which said reasons are herein incorporated by reference.

Claims 1-4 and 6-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Wiesel (U.S. Patent No. 6,287,120; 2001), for the reasons of record set forth at pages 11-12 of the previous Office Action dated October 25, 2006, of which said reasons are herein incorporated by reference.

Claims 1-4 and 6-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Julius (U.S. Patent No. 4,071,955; 1978) or Speaker et al. (U.S. Patent

No. 4,917,892; 1990), for the reasons of record set forth at pages 12-14 of the previous Office Action dated October 25, 2006, of which said reasons are herein incorporated by reference.

Claims 1-4, 6-7, 10-13 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Copelan et al. (U.S. Patent No. 5,133,971; 1992), for the reasons of record set forth at pages 14-15 of the previous Office Action dated October 25, 2006, of which said reasons are herein incorporated by reference.

Claims 1-4 and 6-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Masci et al. (U.S. Patent No. 3,147,182; 1964) in view of Vermeer et al. (U.S. Patent No. 5,624,906; 1997) and in further view of Copelan et al. (U.S. Patent No. 5,133,971; 1992) and in further view of Julius (U.S. Patent No. 4,071,955; 1978) or Speaker et al. (U.S. Patent No. 4,917,892; 1990), for the reasons of record set forth at pages 15-17 of the previous Office Action dated October 25, 2006, of which said reasons are herein incorporated by reference.

Newly amended claims 1 and 10, which now recite the use of a dosage amount of 0.75-3 ml of the topical oral medication, i.e., benzoic acid, are properly included in each of the instant rejection(s) above because the determination of the optimum dosage to treat adverse periodontal conditions with the presently claimed combination would have been a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art because such a person would have considered a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the size of the cotton roll in order to locate the optimal range. Thus, the dosage that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage

amounts are not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

In addition, the concentration of the active ingredient is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Applicant is further reminded that should he rely upon the fact that a particular amount of the claimed active agent is critical to the invention, Applicant must make an objective showing that the claimed range achieves unexpected results relative to the prior art range [*In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)] and that the unexpected results demonstrate a marked improvement over that achieved using the amounts of the prior art such that the difference shown in actually a difference in kind and not just a difference in degree [*In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974)]. Furthermore, Applicant is further advised that should he rely upon unexpected results to patentably distinguish over the prior art, the present claims must be limited to that embodiment which is, in fact, unexpected.

Response to Applicant's Arguments and the Declaration of Milo Novotny under 37 C.F.R. 1.132

Applicant disputes the Examiner's understanding of who is one of ordinary skill in the art and what is his level of experience. Applicant further submits that the Office Action uses the term "skilled artisan" as code for saying "one of extraordinary skill in the art", which is neither present in the statute, nor in the law.

In response thereto, it is noted that "one of ordinary skill in the art" is synonymous with "the skilled artisan". In other words, the skilled artisan is one and the same with one of ordinary skill in the art. As held in *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (see also, e.g., MPEP §2142), the skilled artisan is a hypothetical person with ordinary, *not extraordinary*, skill in the art to which the claimed subject matter pertains and who, of necessity, has the capability to understand the scientific and engineering principles applicable to the pertinent art. This standard of "a person having ordinary skill in the art to which said subject matter pertains" is, in fact, recited in the statute. Please see 35 U.S.C. 103(a), which states, "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to *a person having ordinary skill in the art to which said subject matter pertains*. Patentability shall not be negatived by the manner in which the invention was made."

Applicant's allegation that the Examiner relies upon the standard of an artisan who, according to Applicant at page 11 of the remarks, is 'one of extraordinary skill in the art' is, respectfully, a subjective interpretation of the standard applied by the Examiner. Furthermore, as held in *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983) and also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001), if the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. Accordingly, the Examiner need not specifically quantify the level of skill in the art at the time of the invention when the prior art of record clearly establishes the skill level of the art. In the instant case, the prior art of record is supportive of the fact that the state of the art was such

that one of *ordinary* skill in the art would have been motivated to combine the cited references, not one of *extraordinary* skill in the art.

Applicant relies upon the Declaration of Dr. Novotny in support of the allegation that the Examiner has failed to provided motivation as to why one would select a dry composition and apply it to a cotton roll with an unstated and, therefore, unknown treatment out of Masci et al. Applicant additionally submits that Masci et al. provides a dominant teaching of aqueous solutions by themselves and provides no reason to wet the cotton rolls.

In response to such remarks, Applicant is directed back to Masci et al. at col.8, lines 2-16, which teaches the benefit of the present of water to obtain the antimicrobial activity from the quaternary ammonium salts of the disclosed composition of active ingredients and then goes on to teach the incorporation of the active ingredients into, e.g., cotton rolls. This is clearly an implicit, if not explicit, suggestion to use an aqueous solution of the active composition for application to a cotton roll. The preparation of an aqueous solution incorporated into a cotton roll would obviously be an embodiment where the rolls were "wet". Though the active ingredients may also be employed solely as an aqueous solution or a dry powder, such embodiments do not teach away from the application of an aqueous solution of the active composition to an article such as, e.g., a cotton roll.

In other words, dry compositions applied to dry cotton rolls are but one embodiment of the invention disclosed by Masci et al. The fact that a reference may teach embodiments that differ from Applicant's own invention does not negate the teachings of the reference as a whole and what the reference as a whole would have reasonably suggested to one having ordinary skill in the art at the time of the invention. Picking and choosing elements from a reference that differ from those upon which the Examiner relies in support of the rejection as a means for discounting the case of *prima facie* obviousness made by the Examiner is not persuasive when Applicant does not clearly address the pertinent teachings of the reference upon which the rejection is based.

Furthermore, though Applicant alleges that the prior art reference to Masci et al. does not recognize its usefulness in treating the claimed adverse periodontal conditions, Applicant is reminded that it is not necessary for the prior art references to recognize the same intended therapeutic purpose as Applicant's intended use of the composition in order to meet the claim. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In the instant case, the fact that Applicant intends to apply the cotton roll for the treatment of adverse periodontal conditions of bad breath and gingivitis present in oral soft gingival and sulcus tissues fails to physically or structurally limit the claimed combination of matter such that the claimed use is a patentable distinction over the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has failed to provide any evidence that the prior art product of Masci et al. would *not* be capable of performing the intended use. Furthermore, the fact that Masci et al. suggests the application of the disclosed active ingredients to dental articles suggests its acceptability for use in the mouth, which is a clear basis for asserting that the disclosed product of Masci et al. would, in fact, be capable of performing Applicant's intended use, absent factual evidence to the contrary.

Applicant continues to allege that the Examiner has used her unsupported opinion as the basis for the 103 rejection(s) presented in the previous Office Action. Applicant relies upon *Ex parte Stern* in support of the assertion that the Examiner is required to provide the requisite factual basis and motivation to support the conclusion of obviousness.

This is not persuasive. First, the *prima facie* case of obviousness has been supported not only by prior art references and motivation drawn from such references, but also scientific reasoning. Nowhere in the Office Action did the rejections make conclusory statements that the claimed invention was *prima facie* obvious in the absence of any evidence and motivation. Additionally, nowhere in the Office Action did the rejections take the position that it was the opinion or conjecture of the Examiner that the instant

invention was *prima facie* obvious. Accordingly, in view of the *evidence and motivation* provided by the Examiner, the burden is shifted to Applicant to demonstrate patentable distinction of the claimed invention over the prior art of record.

Second, Applicant's reliance upon the decision rendered in *Ex parte Stern* has been fully considered, but is not relevant to the instant case. Please see the attached text of the decision, which clearly sets forth the error of the Examiner in failing to provide any evidentiary support other than the Examiner's opinion that purification of the disclosed interleukin-2 was "deemed obvious". This is distinctly different than the instant case because the instant Examiner has clearly supported the *prima facie* case of obviousness with evidence and motivation. Accordingly, remarks pertaining to the "unsupported opinion of the Examiner" will not be further considered herein because they do not raise any issues of material fact considering the evidence set forth in the record.

Applicant once again repeats the same arguments against each of the reference individually at pages 13-14 of the remarks. However, as previously stated in the prior Office Action of October 25, 2006, Applicant is reminded that the rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Applicant is clearly does not address the combined teachings of the references as the references were coupled in each of the individual rejections set forth in the prior Office Action, but rather focuses solely on the discrete teachings of each of the cited references and asserts that, since none of the references teach the presently claimed invention in its entirety, that the rejection is improper. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the dental art with regard to the claimed invention. Furthermore, references pertaining to the field of Applicant's endeavor, i.e., the dental arts, would have naturally commended themselves to one of ordinary skill in the art at the time of the invention, absent any factual evidence to the contrary. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*,

642 F.2d 413, 208 UPSQ 871 (CCPA 1981). Accordingly, Applicant's remarks regarding the applicability of each of the individual references, without considering the combination of references set forth in the rejection, will not be further considered herein.

Applicant disputes the Examiner's statement that an express motivation is not required in order to construct a finding of obviousness and further states that, "The PTO is taking the position that all motivation in a medical device case, or chemical case, or perhaps all cases, is not necessary because of the desire of any art to have improved results. That is not the law. Indeed, this is a direct frontal assault on the law of improved results, because that position of the Office in effect says 'If you show improved results, that proves the motivation.' The law is that improved results are strong indicia of patentability, not the right to combine disparate elements out of the prior art, selected by an Examiner's hindsight use of the Applicant's Specification as a parts list and blue print."

In response, Applicant takes the statement that there is no requirement that an express, *written* motivation to combine must appear in the prior art reference before a finding of obviousness out of context. The fact remains that a finding of obviousness may be supported by either an explicitly stated motivation in the prior art *or* an implicit motivation. In other words, the prior art does not need to literally state in words a motivational statement to make a particular combination in order for that combination to have been held to be obvious. As held in *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985), "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or *impliedly* suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." (emphasis added) The Examiner may equally well rely upon an explicit motivation or an implicit motivation to find obviousness. This practice was clearly followed in the Office Action, which provided evidence and motivation for each combination

of references made, and, accordingly, remarks to the contrary are not persuasive and will not be further considered herein.

Furthermore, Applicant argues that the PTO has misapplied the concept of improved results as being the basis for a motivation to combine references, and argues that improved results are indicia of patentability. However, as held in *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983), the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. This is the present case. The desire of the skilled artisan to improve upon what was already known and used in the art based on the advantages and benefits stated in the cited references clearly supports the asserted motivation to make the cited combinations. This statement of "improved results" as made by Applicant overlooks a material fact that is pertinent to conclusions of *prima facie* obviousness: it is not simply *improved results* that are indicia of patentability, it is *unexpectedly improved results* that would not have been reasonably expected by a person of ordinary skill in the art at the time of the invention. As held in *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991), Applicants must show that the results of the claimed product were *greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage*. The mere assertion of an "improved result" alone does not, without more, such as objective evidence, weigh against the obviousness of the claimed invention set forth by the Examiner. As stated in the MPEP at §2141.03[R-2], once the Examiner has produced a *prima facie* case, the burden of coming forward with evidence shifts to the Applicant, who may, for example, submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses *improved properties not expected by the prior art.*

Applicant additionally argues that, "One of ordinary skill in the art does not see in the references any that flexure of the buccinator muscle, e.g., during speaking, acting on and as a result of the presence of the cotton rolls open the sulci so that the antibacterial treatment fluid can target those hidden reservoirs of the bacteria contributing to bad breath." Please see page 15 of Applicant's remarks.

These remarks are clearly directed towards Applicant's repeated assertions that the Examiner has ignored limitations of the claims that Applicant alleges deserve patentable weight. While the Examiner has fully and carefully considered all such limitations of the claims, it remains that the limitations directed to the insertion of the cotton roll into the buccal vestibule and the release of the topical oral medication directly to the affected tissue upon massaging action of the buccinator muscle adjacent to the buccal vestibule to bathe the oral gingival and sulcus tissues and to stimulate saliva production such that the treatment of adverse periodontal conditions of bad breath and gingivitis is achieved are statements of the ultimate function of the dosage unit once it is applied to the oral cavity. However, the claims as written do not presently recite an active claim step to the insertion of the cotton roll into the oral cavity. Accordingly, the limitations recited in, for example, part (c) of claims 1 or 10, are recitations of functions that the composition must be effective to do, but does not require such steps to be performed. It has long been held in patent law that the scope of a claim is not limited by claim language that does not require steps to be performed in order to achieve such a result. Furthermore, it is noted that a composition that constructively meets each and every physical and structural limitation of the claimed invention would be capable of performing such a function when used in the oral cavity, absent any factual evidence to the contrary.

Applicant presents the Declaration of Dr. Milo Novotny under 37 C.F.R. 1.132 in support of the non-obviousness of the claimed invention. Dr. Novotny's Declaration is replete with statements of his personal opinion regarding the non-obviousness of the claimed invention and why one of ordinary skill in

the art at the time of the invention, in his opinion, would not have been directed to combining the references to arrive at the instantly claimed invention.

While Dr. Novotny's extensive experience in the dental profession has been duly and respectfully noted, it remains that statements of his personal opinion do not raise issues of material fact and fail to present objective evidence of non-obviousness. Opinions of a practitioner in the art do not equate to evidence in the record. In the absence of any facts or evidence, the Declaration of Dr. Novotny amounts to no more than an opinion as to the propriety of the legal conclusion(s) set forth by the Examiner in the previous Office Action and is, therefore, not entitled to any weight, nor is persuasive because it does not address the evidence in the record that supports the conclusion of *prima facie* obviousness.

Furthermore, Dr. Novotny appears to be making a comparison between the effectiveness of the claimed invention versus the effectiveness of conventional mouthwash in treating bad breath conditions. However, this comparison is between two completely different prior art products and, thus, would have been reasonably expected by one of ordinary skill in the art to result in a difference in properties. What Applicant fails to address is whether the claimed invention shows an unexpected result over the closest prior art. As held in *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979), an affidavit or declaration under 37 C.F.R. 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a *prima facie* case of obviousness. In the absence of such a comparison, the fact that the claimed product shows a different effect than a distinctly different product (i.e., a conventional mouthwash) is not persuasive in establishing non-obviousness.

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art that is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and MPEP §716.02(d) - §716.02(e). See *In re Blondel*, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and *In re Fouche*, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was

found sufficient to rebut a *prima facie* case of obviousness. See also MPEP §716.02(b)[R-2](III). Failure to provide objective evidence of unexpected properties does not support mere allegations and statements of unexpected results. In other words, the fact that Dr. Novotny deems the results "unexpected", in his opinion, constitutes mere argument and fails to be indicative of non-obviousness and patentability in the absence of objective evidence.

Furthermore, it is noted that Dr. Novotny's own experience with the claimed product contained a boric acid mouthwash, not benzoic acid, which is the species of topical oral medication under examination. Accordingly, even if Dr. Novotny's experience with the claimed product did amount to an unexpected result, of which such a statement is not to be construed as an admission that it does show an unexpected result, the results are not commensurate in scope with the claimed subject matter under examination because they do not address the efficacy of the elected oral medication of benzoic acid in the claimed cotton roll product over the prior art.

Dr. Novotny further states that, in his experience, he has never seen cotton rolls impregnated with the binary mixture of quaternary ammonium salts, wet or dry, as taught by Masci et al. and further asserts that cotton rolls used in the dental field are dry and are not used to deliver medications. These statements are also not persuasive. The fact that Dr. Novotny himself has never seen a cotton roll as taught by Masci et al. does not negate the teachings of Masci et al. Masci et al. clearly contemplated and received a patent for his disclosure and, therefore, his teachings properly constitute prior art against the claimed invention. In other words, the fact that Dr. Novotny has not seen a cotton roll of the type disclosed by Masci et al. used does not mean that his invention has ceased to exist in the art. Furthermore, the fact that the dental arts commonly use dry cotton rolls is not supportive of the allegation that these are the *only* uses of cotton rolls known to one of ordinary skill in the art at the time of the invention. In fact, one of ordinary skill in the medical, and even the dental arts, would likely take issue with this allegation, since cotton rolls are

frequently used to apply medicinal agents, including antibiotic solutions, at surgical sites, oral or otherwise.

In keeping with Applicant's discussion of the references individually, Dr. Novotny performs this same analysis of the individual references in his Declaration. As stated *supra*, rejections under 35 U.S.C. 103(a) are based upon combinations of references. A failure to address the combined teachings of the references as the references were coupled in each of the individual rejections set forth in the prior Office Action, but rather focusing solely on the discrete teachings of each of the cited references, is not persuasive. Moreover, assertions that the rejection is improper because none of the references teach the presently claimed invention in its entirety are also not persuasive because the references are relied upon in combination and are not meant to be considered separately as in a vacuum. Both Applicant and Dr. Novotny are reminded that ignoring the broader disclosure of the reference and what it would have suggested to one of ordinary skill in the art at the time of the invention in order to support a case of non-obviousness is not persuasive when it clearly does not address the evidence that the references provide in support of the *prima facie* case of obviousness. Accordingly, Dr. Novotny's remarks regarding the applicability of each of the individual references, without considering the evidence relied upon in support of the *prima facie* case of obviousness and the combination of references set forth in the rejection, will not be further considered herein.

Accordingly, in view of the foregoing, when all of the evidence is considered, the totality of rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness.

For these reasons, the claims remain properly rejected under 35 U.S.C. 103(a) and the rejections are **maintained**.

Conclusion

Rejection of claims 1-4 and 6-15 remains proper and is **maintained**.

Claim 5 remains pending but **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

Finality of the restriction requirement is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 12, 2007

4/14/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER